



**Bristol-Myers Squibb Company**

State Rd. #3, KM. 77.5 Humacao, Puerto Rico 00791

September 7, 2016

**VIA EMAIL (MARTINEZ.SOCORRO@EPA.GOV) & FEDEX**

Socorro Martinez  
U.S. Environmental Protection Agency, Region 2  
Caribbean Environmental Protection Division  
City View Plaza – Suite 7000  
#48 RD. 165 KM. 1.2  
Guaynabo, Puerto Rico 00968-8069

**Re: Bristol-Myers Squibb Manufacturing Company  
Humacao, Puerto Rico Facility  
EPA ID No. PRD090021056  
Contained-In Determination**

Dear Ms. Martinez:

As you know, the Bristol-Myers Squibb Manufacturing Company (“BMSMC”) Humacao, Puerto Rico facility (the “Facility”) has been conducting a Corrective Measures Study pursuant to its Resource Conservation and Recovery Act (RCRA) Part B permit. On-site investigations have resulted – and will continue to result – in environmental media, i.e., soil and groundwater, that require active management. As such, BMSMC provides this notice of intent to apply the United States Environmental Protection Agency (EPA) RCRA contained-in policy in waste management decision making for constituents detected in soil and groundwater.

Contaminated environmental media, of itself, is not hazardous waste and, generally, is not subject to regulation under RCRA. Contaminated environmental media can become subject to regulation under RCRA if they “contain” hazardous waste. EPA generally considers contaminated environmental media to contain hazardous waste: (1) when they exhibit a characteristic of hazardous waste; or, (2) when they are contaminated with concentrations of hazardous constituents from listed hazardous waste that are above health-based levels (EPA 1998). The contained-in policy allows EPA to use site-specific, media-specific, and constituent-specific health-based criteria to decide when hazardous waste is not “contained-in” environmental media. For the evaluation of whether environmental media generated during the ongoing Corrective Measures Study contains hazardous waste BMSMC proposes to use the following EPA health-based criteria:

- RCRA Toxicity Characteristic (TC) values at 40 C.F.R. § 261.24
- EPA Regional Removal Management Levels for tap water and industrial soil at <https://www.epa.gov/risk/regional-removal-management-levels-chemicals-rmls>

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The attached table provides health-based criteria for constituents detected in soil and groundwater at the facility. BSMC will use these criteria in the following approach to make contained-in determinations:

- Characteristic Waste (“D-Codes”) - BSMC will rely on the TC values tabulated at 40 C.F.R. § 261.24. This means that water would be considered non-hazardous (contained-out) if the constituent concentration in water falls below the TC value for that constituent. Similarly, soil would be considered non-hazardous if the constituent concentration resulting from the Toxicity Characteristic Leaching Procedure (TCLP) falls below the TC value for that constituent. Conversely, soil or water that exhibits the toxicity characteristic of hazardous waste (i.e., constituent concentration that exceeds its TC value) will be managed as a RCRA hazardous waste.
- Listed Waste (“F, P and U Codes”) – BSMC will rely on EPA’s Regional Removal Management Levels (“RMLs”) as health-based criteria for evaluating whether soil or groundwater contain hazardous waste. EPA RMLs provide health-based criteria for potential carcinogens at a one-in-ten thousand ( $10^{-4}$ ) risk level, and for non-carcinogens at hazard quotient (HQ) of 3. Because the Facility is in active industrial operation, BSMC proposes to use the Industrial Soil RMLs for evaluation of soil. For groundwater, BSMC proposes to use the Tapwater RMLs. This means that water would be considered non-hazardous (contained-out) if the constituent concentration in water falls below the RML for that constituent. Similarly, soil would be considered non-hazardous if the constituent concentration falls below the Industrial RML for that constituent. Conversely, soil or water that contains a constituent concentration that exceeds its RML will be managed as a RCRA hazardous waste.
- F003 - This listing is based solely on the characteristic of ignitability. As such, F003 waste is not a hazardous waste if the waste no longer exhibits the ignitability characteristic. As indicated in the attached table, this distinction applies to acetone, ethylbenzene, methanol, methyl isobutyl ketone, and xylenes. For solids such as soil, EPA (1980) defines ignitability as the property of thermal instability, and relies on generator knowledge since neither EPA nor RCRA have a standardized test method for ignitability of solids. Based on knowledge and experience, BSMC considers soil as contained-out for the ignitability characteristic. For liquids, such as groundwater, contained out applies to solutions containing less than 24 percent alcohol by volume and a flash point less than 60 degrees Celsius (or 140 degrees Fahrenheit).

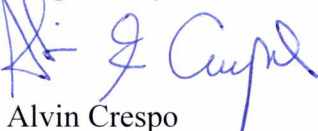
The approach described above proposes criteria without consideration of treatment and/or disposal endpoints.

September 7, 2016

Please do not hesitate to contact me if you need any additional information. Thank you for your time and consideration.

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision according to a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

Respectfully submitted,



Alvin Crespo  
EHS Director, Humacao Operations

Enclosure

cc: RCRA Record Center

EPA. 1980. Background Document, Resource Conservation and Recovery Act, Subtitle C – Identification and Listing of Hazardous Waste, Section 261.21 – Characteristic of Ignitability.

EPA. 1998. Management of Remediation Waste under RCRA. EPA 530-F-98-026.

EPA. 2004. Local Limits Development Guidance. EPA 833-R-04-002A.



**EPA Health-Based Criteria for RCRA Contained-In Evaluation**

Constituent	CAS No.	RCRA Hazard Code	EPA Waste Code	RCRA Toxicity Characteristic <sup>1</sup> (mg/l)	EPA Regional Removal Management Level - Tap Water <sup>2</sup> (mg/l)	EPA Regional Removal Management Level - Industrial Soil <sup>2</sup> (mg/kg)
<i>Potential Carcinogens (Oral Exposure)</i>						
Benzene	71-43-2	I,T	D018	0.5	0.046	510
Benzyl Chloride	100-44-7	H	P028	-	0.006	320
Chloroform	67-66-3	T	D022	6	0.022	140
4-Chloroaniline	106-47-8	H	P024	-	0.037	1,100
1,4-Dioxane	123-91-1	T	U108	-	0.046	2,400
Methylene Chloride	75-09-2	T	F002	-	0.32	9,500
Tetrachloroethene	127-18-4	T	F002	0.7	0.12	1,200
Trichloroethene	79-01-6	T	F002	0.5	0.0085	56
Vinyl Chloride	75-01-4	T	F002	0.2	0.0019	170
<i>Non-Carcinogens (Oral Exposure)</i>						
Acetone	67-64-1	I	F003	-	42	2,000,000
Chlorobenzene	108-90-7	T	D021	100	0.23	4,000
1,4-Dichlorobenzene	106-46-7	T	D027	7.5	0.048	1,100
1,2-Dichloropropane	78-87-5	T	U083	-	0.025	200
2,4-Dimethylphenol	105-67-9	T	U101	-	1.1	49,000
Ethylbenzene	100-41-4	I	F003	-	0.15	2,500
Isobutanol	78-83-1	I,T	F005	-	18	1,100,000
Methanol	67-56-1	I	F003	-	61	3,700,000
Methyl Isobutyl Ketone	108-10-1	I	F003	-	19	420,000
Tetrahydrofuran	109-99-9	I,T	U213	-	10	105,000
Toluene	108-88-3	I,T	F005	-	3.3	140,000
Xylenes	1330-20-7	I	F003	-	0.58	7,500

**Table Notes:**

1 Code of Federal Regulations, Title 40 - Protection of Environment, Part 261 - Identification and Listing of Hazardous Waste, Subpart 261.24 - Toxicity Characteristic

2

EPA. 2016. Regional Removal Management Levels (RMLs) User's Guide. [www.epa.gov/risk/regional-removal-management-levels-rmls-users-guide](http://www.epa.gov/risk/regional-removal-management-levels-rmls-users-guide). RMLs set at 10<sup>-4</sup> risk level for potential carcinogens, and a hazard quotient of 3 for non-carcinogens.

- Not available for constituent

Yellow highlight identifies BMSMC-proposed groundwater Contained-In Criteria

Shading indicates constituent listed as F003 waste for ignitability. The F003 listing is based solely on the characteristic of ignitability. As such, F003 waste is not a hazardous waste if the waste no longer exhibits the ignitability characteristic. As indicated in the attached table, this distinction applies to acetone, ethylbenzene, methanol, methyl isobutyl ketone, and xylenes. For solids such as soil, EPA (1980) defines ignitability as the property of thermal instability, and relies on generator knowledge since neither EPA nor RCRA have a standardized test method for ignitability of solids. Based on knowledge and experience, BMSMC considers soil as contained-out for the ignitability characteristic. For liquids, such as groundwater, contained out applies to solutions containing less than 24 percent alcohol by volume and a flash point less than 60 degrees Celsius (or 140 degrees Fahrenheit). ), as determined by a Pensky-Martens Closed Cup Tester, using the test method specified in ASTM Standard D 93-79 or D 93-80 (incorporated by reference, see § 260.11), or a Setaflash Closed Cup Tester, using the test method specified in ASTM Standard D 3278-78 (incorporated by reference, see § 260.11).

**RCRA Hazard Codes**

T - Toxicity

H - Acutely Hazardous (toxicity)

I - Ignitability